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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,955	04/15/2004	Kenneth T. Heruth	1023-362US01	8230
28863 7590 06/27/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,955

Applicant(s)

HERUTH ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-27 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10, 13, 24 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 12, 14, 15, 17-23, 25-27, 69 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070102</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/13/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 04/13/2007, amended claim(s) 1, canceled claim(s) 16 and 28-68, and new claim(s) 69-71 is/are acknowledged. The current rejections of the claim(s) 1-6, 8, 9, 11, and 17-27 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

3. Claims 24 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2006.

4. The Examiner notes claims 24 and 71 are withdrawn from further consideration as being drawn to nonelected Species AA "user-interface" embodiment.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statement(s) (IDS) submitted on 01/02/2007 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Objections

7. Claim 3 is objected to because of the following informalities: the positive recitation of "comprising" in line 2 appears to be a typographical and/or grammatical error. The Examiner notes it appears Applicant intended it to positively recite "comprises". Appropriate correction is required.

8. Claim 69 is objected to because of the following informalities: the positive recitation of "each of the plurality of therapy parameter sets" in lines 14 and 17 appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: (a) the structural relationship between the "values of at least one sleep quality metric" of line 6 and the "value of each of the least one sleep quality metric" of lines 14-15 and (b) the structural relationship between the "values of at least one sleep quality metric" of line 6 and the "at least one activity metric value" of lines 17-18. Although it is clear that the second recitations are associated with the therapy parameter set, it is indefinite if the values in both cases (a) and (b) are distinct limitations or if they are duplicate structure and in the event that they are distinct limitations how they differ.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-23, 25-27, 69, and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US 2004/0111040 A1).

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14. Claims 1-3, 5, 6, 8-9, 11-12, 14-15, and 17-27 are rejected under 35

U.S.C. 102(e) as being anticipated by Ni et al (US 2004/0111041 A1).

15. For claims 1 and 69, Ni et al discloses a method, comprising:

- monitoring a plurality of physiological parameters (620, 625, and 630) of a patient via an implantable medical device (100, 200 and 300), wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity (e.g. at least breathing or posture) (paragraphs 39, 52, and 77);
- determining when the patient is attempting to sleep via sensors (130, 134, 320, and 321) (as best seen in Figures 5B and 6) (paragraphs 7, 11, 53-57, 77, and 84-90);
- determining values of at least one sleep quality metric (550) that is indicative of sleep quality based on values of the at least one physiological parameters when the patient is attempting to sleep (565) (as best seen in Figure 5A) (paragraphs 47-48, 53-57, and 84-90);
- periodically determining an activity level (paragraphs 42-43 and 51) of the patient based on the at least one physiological parameters and a determination that the patient is not attempting to sleep (570) (paragraph 106);
- determining a value of at least one activity metric based on the activity levels determined when the patient is not attempting to sleep (paragraphs 132-134); and
- associating the sleep quality metrics and the activity level metrics with a therapy parameter set (587 and 597) via elements 340 and 350 (paragraphs 62-63 and 72).

16. For claim 2, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the patients sensed activity levels as cited above) that the patient is attempting to sleep (paragraph 106).

17. For claim 3, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep comprises determining when the patient is recumbent (as best seen in Figures 5B and 6) (paragraphs 97, 106, and 119).

18. For claims 5 and 6, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (Figures 5B and 6) (paragraphs 11, 77, and 95-97) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (paragraphs 48, 57, 84-85 and 95).

19. For claims 8 and 9, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood pressure (paragraph 52).

20. For claim 11, Ni et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the

physiological parameters; and determining an amount of time between the first and second times (as best seen in Figures 7A, 7B9, 14, and 15).

21. For claim 12, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is asleep based on at least one of the physiological parameters (510); and determining an amount of time that the patient is asleep during a period (as best seen in Figures 7A, 7B9, 14, and 15).

22. For claim 14, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is within a sleep state based on at least one of the physiological parameters (510); and determining an amount of time that the patient was within the sleep state (as best seen in Figures 7A, 7B9, 14, and 15).

23. For claim 15, Ni et al discloses a method wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state (paragraphs 2-4).

24. For claim 17, Ni et al discloses a method wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels (paragraphs 46 and 99).

25. For claim 18, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing the at least one of the mean and the median activity level to at least one threshold (paragraph 99); and selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison (paragraphs 47 and 92).

26. For claim 19, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and

determining at least one of a percentage of time above the threshold and a percentage of time below the threshold (paragraphs 46 and 99) (as best seen in Figures 7A, 7B9, 14, and 15).

27. For claim 20, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and determining an average length of time that consecutively determined activity levels were above the threshold (paragraphs 46 and 99) (as best seen in Figures 7A, 7B9, 14, and 15).

28. For claims 21-23 and 70, Ni et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (as best seen in Figures 7A, 7B9, 14, and 15); (b) the medical device delivers a therapy (paragraphs 72-74) to the patient according to a plurality of therapy parameter sets, the method further comprising: associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set; for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set; and (c) presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values (paragraphs 75-76).

29. For claim 25, Ni et al discloses a method wherein a medical device comprises an implantable medical device (paragraph 11).

30. For claims 26 and 27, Ni et al the claimed methods of using an implantable medical device including an implantable neurostimulator (202).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

32. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

33. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al in view of Sheldon (US 5,593,431). Ni et al discloses the claimed invention, including monitoring posture via accelerometers, except for explicitly disclosing monitoring a signal from each of a plurality of orthogonally aligned accelerometers and determining when the patient is recumbent based on a DC component of each of the signals.

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Sheldon teaches a medical device comprising monitoring a signal from each of a plurality of orthogonally aligned accelerometers and determining when the patient is recumbent based on a DC component of each of the signals (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device as taught by Ni et al, with the medical device as taught by Sheldon for the purpose of monitoring posture.

Response to Arguments

34. Applicant's arguments with respect to claims 1-6, 8, 9, 11, 12, 14, 15, 17-23, 25-27, 69, and 70 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra

Examiner, Art Unit 3736


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